

## **REMARKS**

Applicants note that the Amendment filed January 16, 2004 has been entered.

Claims 60-76 were pending in the above-referenced application.

### **I. Amendments to the Claims**

Claim 64 has been amended.

Claim 65 has been cancelled without prejudice or disclaimer of the subject matter recited therein.

Accordingly, claims 60-64 and 66-76 are currently pending in this application.

### **II. Rejections under 35 U.S.C. § 103**

Applicants gratefully acknowledge that the previous rejection of the claims under 35 U.S.C. § 103, for allegedly being unpatentable over Ledbetter et al. (EP0440373) in view of Ledbetter et al. (U.S. Patent No.: 6,010,902) and Chang (U.S. Patent No.: 6,129,916) (Office Action, page 2, paragraph 5) has been withdrawn by the Examiner because the amended claims are drawn to methods which employ the use of anti-CD3 and anti-CD28 antibodies which are covalently attached to the same surface to induce the population of T cells to proliferate to sufficient numbers for use in therapy (Office Action, page 2, section 2).

### **III. Rejections under 35 U.S. C. § 112, first paragraph**

Claim 64 stands rejected under 35 U.S.C. § 112, first paragraph, for allegedly not providing enablement for determining the level of expression of any cell surface molecule (Office Action, page 2, section 4).

Claim 64 also stands rejected 35 U.S.C. § 112, first paragraph, for allegedly not containing a written description of the genus of cell surface molecules set forth in claim 65, which Applicants interpreted to mean claim 64 (Office Action, page 3, section 5).

The Examiner invited the Applicants to limit the invention to B7-1 and B7-2 as set forth in claim 66 to obviate this rejection (Office Action, page 5, fourth paragraph). Again, Applicants noted that the proper claim amendment refers to claim 65 instead of claim 66.

Without acquiescing to the propriety of these rejections, and solely to expedite prosecution of the instant Application, Applicants have amended claim 64, by incorporating the limitations of claim 65, in line with the Examiner's suggestion.

Applicants aver that these rejections under 35 U.S.C. § 112, first paragraph (enablement and written description) have been rendered moot. Accordingly, Applicants respectfully request the Examiner reconsider and withdraw these rejections.

#### **IV. Rejections under the doctrine of obviousness-type double patenting**

Claims 60-76 remain rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 6,352,694 (Office Action, page 6, paragraph 6), and over claims 1-29 of U.S. Patent No. 6,534,055 (Office Action, page 5, section 7).

Without acquiescing to the propriety of these rejections, and solely with the intent to expedite prosecution of the instant Application, Applicants submit herewith a Terminal Disclaimer over U.S. Patent No. 6,352,694 (Appendix A), and a Terminal Disclaimer over U.S. Patent No. 6,534,055 (Appendix B), in compliance with 37 C.F.R. § 1.321, to obviate the rejections under the doctrine of obviousness-type double patenting.

Accordingly, the Examiner is respectfully requested to reconsider the application in light of the above, and withdraw the rejections under the doctrine of obviousness-type double patenting.

**V. Provisional Rejections under the doctrine of obviousness-type double patenting**

Claims 60-76 remain provisionally rejected under the doctrine of obviousness-type double patenting as being unpatentable over copending claims of USSN 08/253,964, USSN 08/592,711, USSN 09/350,202; and USSN 09/553,865 (Office Action, page 5, section 6).

Applicants gratefully note that the Examiner has withdrawn the previous provisional rejection under the doctrine of obviousness type double patenting over USSN 09/183,055, because the claims of USSN 09/183,055 are patentably distinct as they include anti-CD9 antibodies to stimulate CD8+ T cells.

Upon entry of the instant amendment, the provisional double patenting rejections will be the only remaining rejections in the instant application. Thus, the Examiner is respectfully requested, in accordance with MPEP § 804, to withdraw the provisional obviousness type double patenting rejections in the instant application and permit the instant application to issue as a patent, thereby converting the “provisional” double patenting rejection in the other applications into a double patenting rejection at the time the instant application issues as a patent.

**VI. Request to Examiner**

The Examiner is respectfully requested to clarify for Applicants whether a dependent claim of claim 62 reciting that the anti-human CD28 monoclonal antibody is 9.3 (ATCC No. HB10271) would be allowable.

Applicants have contacted the ATCC to determine whether the 9.3 antibody (ATCC No. HB 10271) was publicly available. Ms. Tanya Nunnally, a Patent Specialist at the ATCC, stated that HB-10271 has been released for distribution and is available for order from the ATCC Customer Service Department at 1-800-638-6597 (*see*, Appendix C).

Accordingly, Applicants respectfully contend that they should be entitled to claim a method of claim 60, wherein the anti-CD28 antibody is the 9.3 antibody (ATCC No. HB-10271).

**VII. Conclusion**

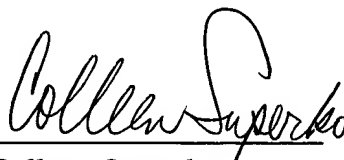
Applicants believe that all of the outstanding rejections of record have been overcome by amendment and/or argument. Accordingly, the claims are now believed to be in condition for allowance. Applicants respectfully request that the Examiner issue a timely Notice of Allowance.

No fees are believed to be due in connection with this correspondence. If any fees are due, please charge any payments due, or credit any overpayments, to our Deposit Account No. 08-0219.

The Examiner is invited to telephone the undersigned at the telephone number given below in order to expedite the prosecution of the instant application.

Respectfully submitted,

Dated: May 3, 2004

  
Colleen Superko  
Reg. No. 39,850

HALE AND DORR LLP  
60 State Street  
Boston, MA 02109  
Tel.: (617) 526-6564  
Fax: (617) 526-5000

**APPENDIX A**

Terminal Disclaimer over U.S. Patent No. 6,352,694

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	09/349,915	Art Unit:	1644
Applicant:	June <i>et al.</i>	Examiner:	Phillip Gambel
Date Filed:	July 8, 1999	Conf. No.	7335
Docket No.	36119.125US10	Cust. No.	23483
Title:	Methods for Selectively Stimulating Proliferation of T Cells		

**CERTIFICATION UNDER 37 C.F.R. § 1.10**

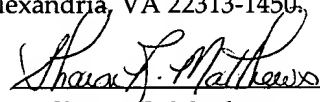
I hereby certify that this correspondence is being deposited with the United States Postal Service as "Express Mail Post Office to Addressee" Service under 37 C.F.R. § 1.10 on the date indicated below and is addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

EV 22520175005

Express Mail No.

5/3/04

Date of Deposit



Sharon R. Matthews

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TERMINAL DISCLAIMER**

Dear Sir:

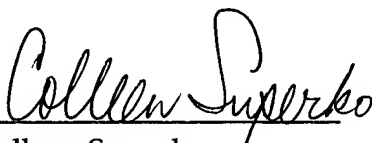
Pursuant to 35 U.S.C. § 253 and 37 C.F.R. § 1.321, Genetics Institute, Inc., (now Wyeth) hereby disclaims the terminal part of any patent granted on the above-identified application, which would extend beyond the expiration date of the full statutory term of United States Letters Patent No. 6,352,694. Any patent granted on the subject application shall be enforceable only for and during such period that such patent is commonly owned with U.S. Patent No. 6,352,694. Genetics Institute, Inc. (now Wyeth) does not disclaim any portion of the term of such patent that would extend

beyond invalidation or other premature termination of enforceability of U.S. Patent No. 6,352,694.

Please charge our Deposit Account No. 08-0219 for the petition fee pursuant to 37 C.F.R. § 1.20(d).

Respectfully submitted,

Date: May 3, 2004

  
Colleen Superko  
Registration No. 39,850

Hale and Dorr LLP  
60 State Street  
Boston, MA 02109  
Tel: (617) 526-6564  
Fax: (617) 526-5000



**APPENDIX B**

Terminal Disclaimer over U.S. Patent No. 6, 534,055

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	09/349,915	Art Unit:	1644
Applicant:	June <i>et al.</i>	Examiner:	Phillip Gambel
Date Filed:	July 8, 1999	Conf. No.	7335
Docket No.	36119.125US10	Cust. No.	23483
Title:	Methods for Selectively Stimulating Proliferation of T Cells		

**CERTIFICATION UNDER 37 C.F.R. § 1.10**

I hereby certify that this correspondence is being deposited with the United States Postal Service as "Express Mail Post Office to Addressee" Service under 37 C.F.R. § 1.10 on the date indicated below and is addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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5/3/04  
Date of Deposit

Sharon R. Matthews  
Sharon R. Matthews

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TERMINAL DISCLAIMER**

Dear Sir:

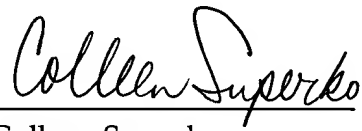
Pursuant to 35 U.S.C. § 253 and 37 C.F.R. § 1.321, Genetics Institute, Inc., (now Wyeth) hereby disclaims the terminal part of any patent granted on the above-identified application, which would extend beyond the expiration date of the full statutory term of United States Letters Patent No. 6,534,055. Any patent granted on the subject application shall be enforceable only for and during such period that such patent is commonly owned with U.S. Patent No. 6,534,055. Genetics Institute, Inc. (now Wyeth) does not disclaim any portion of the term of such patent that would extend

beyond invalidation or other premature termination of enforceability of U.S. Patent No. 6,534,055.

Please charge our Deposit Account No. 08-0219 for the petition fee pursuant to 37 C.F.R. § 1.20(d).

Respectfully submitted,

Date: May 3, 2004

  
Colleen Superko  
Registration No. 39,850

Hale and Dorr LLP  
60 State Street  
Boston, MA 02109  
Tel: (617) 526-6564  
Fax: (617) 526-5000

**APPENDIX C**

Copy of Correspondence with Ms. Tanya Nunnally at the ATCC regarding the availability of the 9.3 antibody (ATCC No. HB-10271).

Koipally, Joseph

From: Nunnally, Tanya [nunnally@atcc.org]  
Sent: Wednesday, August 27, 2003 4:52 PM  
To: Koipally, Joseph  
Subject: RE: Patent Deposit HB-10271

Dear Dr. Koipally,

The item you have requested, HB-10271, has been released for distribution. To order this item please contact our Customer Service Department at: 1-800-638-6597. If you need further assistance please contact me. Thank you.

Tanya Nunnally

-----Original Message-----

From: Koipally, Joseph [mailto:Joseph.Koipally@haledorr.com]  
Sent: Monday, July 07, 2003 4:38 PM  
To: Nunnally, Tanya  
Subject: RE: Patent Deposit HB-10271

Dear Ms. Nunnally,

I recently found a reference to the 9.3 antibody (ATCC No. HB 10271) in US patent No. 5,521,288 (Linsley, Ledbetter et al.) at column 15, l. 47. Is this sufficient to obtain a statement from ATCC saying that this antibody is readily available to the public and that all restrictions imposed by the depositor on the availability to the public of the deposited material have been irrevocably removed.

Please let me know.

Thanks very much.

Best regards,  
Joseph

-----Original Message-----

From: Nunnally, Tanya [mailto:nunnally@atcc.org]  
Sent: Monday, June 30, 2003 4:54 PM  
To: Koipally, Joseph  
Subject: RE: Patent Deposit HB-10271

Dear Dr. Koipally,

I will be glad to contact the depositor for you. I will inform you of their response as soon as I have one. Thank you.

Tanya

-----Original Message-----

From: Koipally, Joseph [mailto:Joseph.Koipally@haledorr.com]  
Sent: Monday, June 30, 2003 4:52 PM  
To: Nunnally, Tanya  
Subject: RE: Patent Deposit HB-10271

Dear Ms. Nunnally:

EXPRESS MAIL LABEL NO. EU 22520175005  
DATE OF DEPOSIT 5/3/04

Thank you very much for your reply. Could I ask you to contact the depositor to find out whether a pertinent US patent referencing the 9.3 antibody has issued and if not if he/she would have any problem releasing the deposit.

Thank you once again for your assistance in this matter.

Sincerely,  
Joseph

-----Original Message-----

From: Nunnally, Tanya [mailto:nunnally@atcc.org]  
Sent: Monday, June 30, 2003 4:26 PM  
To: Koipally, Joseph  
Subject: RE: Patent Deposit HB-10271

Dear Dr. Koipally,

Unfortunately since the item is still restricted, all information concerning it and it's depositor remains confidential. I can contact the depositor on your behalf. Other than that the only thing I can advise is to refer back to the person(s) or institution listed on the European patent application. If I can be of assistance some other way please let me know. Thank you.

Tanya

-----Original Message-----

From: Koipally, Joseph [mailto:Joseph.Koipally@haledorr.com]  
Sent: Friday, June 27, 2003 12:52 PM  
To: Nunnally, Tanya  
Subject: RE: Patent Deposit HB-10271

Dear Ms. Nunnally,

Thank you for your prompt response. HB 10271 was described in a published European patent EP 0 440 373. Could you let me know the name and contact information for the person who has deposited HB 10271?

Thanks very much.

Best,  
Joseph

-----Original Message-----

From: Nunnally, Tanya [mailto:nunnally@atcc.org]  
Sent: Friday, June 27, 2003 12:23 PM  
To: Koipally, Joseph  
Subject: Patent Deposit HB-10271

Dear Dr. Koipally,

Thank you for your inquiry. The item you have mentioned, HB-10271, is not yet available for public distribution. It can only be distributed under the following conditions:

- (1) a U.S. patent issues, and we are so notified;
- (2) a pertinent patent office instructs us to make a sample available to a specific investigator; or
- (3) the depositor authorizes us to make a sample available to a specific investigator.

To the best of my knowledge we have not been informed by the depositor of the issuance of a pertinent U.S. patent. If you believe the

pertinent U.S. patent has issued please provide us with the patent number. We will contact the depositor to verify the information and ask for permission to release the strain. You may also contact the depositor directly to request permission to release the strain. If you have any further questions please let me know. Thank you.

Tanya Nunnally  
Patent Specialist  
American Type Culture Collection  
Phone: 703-365-2721  
Fax: 703-365-2745  
E-mail: nunnally@atcc.org

-----Original Message-----

From: joseph.koipally@haledorr.com [mailto:joseph.koipally@haledorr.com]  
Sent: Friday, June 27, 2003 11:06 AM  
To: tech@atcc.org  
Subject: Website Email

Dear Sir/Madam,  
I am a technology specialist at Hale & Dorr LLP in Boston. We are prosecuting a patent that describes monoclonal antibody 9.3 (ATCC No. HB 10271) which was not deposited by us. The USPTO has requested that we provide information regarding availability of this reagent. In particular, the Examiner at the USPTO would like for us to show that the 9.3 antibody is readily available to the public and that all restrictions imposed by the depositor on the availability to the public of the deposited material was irrevocably removed upon the granting of a patent to the depositor. Would it be possible for ATCC to provide us with such a statement regarding this deposit (ATCC No. HB 10271). I would greatly appreciate hearing from you.

Thanks very much.

Best,  
Joseph Koipally, Ph.D.

Item Number: HB 10271

Joseph Koipally  
Hale & Dorr LLP  
60 State Street,  
Boston, MA 02109 USA